

Reference: 2024-010M

16 January 2025

## URGENT - FIELD SAFETY NOTICE

To user of **Olympus Single Use Guide Sheath Kits**

Product Name	Model/Catalog Number	Lot Number(s)
Single Use Guide Sheath Kit K-201 2.0MM Channel Set: Guide Sheath, Biopsy Forceps, Cytology Brush	K-201	All
Single Use Guide Sheath Kit K-202 2.0MM Channel Set: Guide Sheath, Biopsy Forceps	K-202	All
Single Use Guide Sheath Kit K-203 2.6MM Channel Set: Guide Sheath, Biopsy Forceps, Cytology Brush	K-203	All
Single Use Guide Sheath Kit K-204 2.6MM Channel Set: Guide Sheath, Biopsy Forceps	K-204	All

### **Re: Olympus reminds users to closely follow the Instructions for Use (IFU) for the Single Use Guide Sheath Kits**

Attention: **Endoscopy Department, Bronchoscopy Suite, Pulmonology, Risk Management**

Dear Healthcare Professional:

Olympus is writing to inform you of a Field Safety Notice pertaining to the Single Use Guide Sheath Kits, models K-201, K-202, K-203, and K-204. These instruments have been designed to be used with an Olympus endoscope to collect cells or tissue specimens in the respiratory organs.

#### **Reason for Action:**

Olympus conducted an investigation into the Single Use Guide Sheath Kits after receiving complaints that the radiopaque tip of the guide sheath component (see Figure 1 below), fell off into the patient. Since July 2021, Olympus has received 32 complaints involving intraoperative disassociation of the guide sheath radiopaque tip in which the tip fell off into the patient. Of these 32 complaints, 26 were reported as serious injuries, and 6 were reported as malfunctions. The preliminary findings from Olympus' investigation have identified that the disassociation of the tip from the guide sheath is likely the result of excessive force applied when inserting instruments into the guide sheath, and/or damage to the distal end of the sheath.

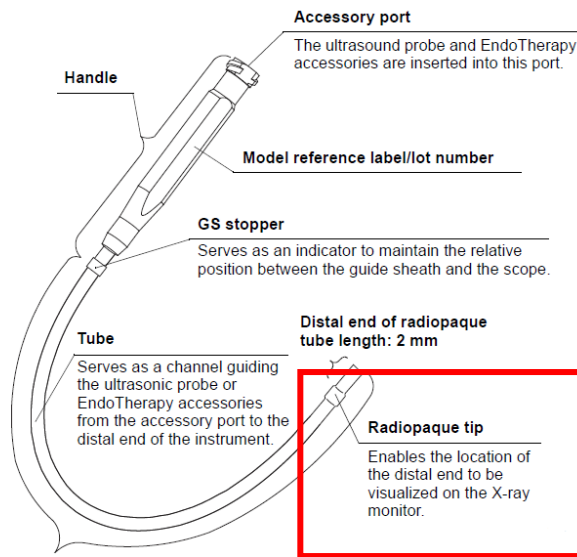


Figure 1: Single Use Guide Sheath (models SG-200C and SG-201C)

Olympus reminds users to closely follow the Instructions for Use (IFU) for the Single Use Guide Sheath Kits, especially the Inspection directions detailed in sections 9 to 9.2 of the IFU, and the Warnings and Cautions listed in section 9.3 Operation, which instruct users not to force instruments if resistance is encountered. Forcing instruments through the guide sheath can contribute to disassociation of the guide sheath radiopaque tip.

**Warning:** Before use, prepare and inspect the instruments as instructed below. Should any irregularity be observed, do not use the instrument but use a spare instead. Damage or irregularity may compromise patient or operator safety by posing an infection-control risks, tissue irritation, perforation, bleeding or mucous membrane damage, and may result in more severe equipment damage.

**Caution:** Do not use excessive force in using the instruments. This could damage the instruments.

**Warning:** Do not force the instrument if resistance to insertion is encountered. Reduce the angulation until the instrument passes smoothly. Forcing the instrument could cause patient injury, such as punctures, hemorrhages or mucous membrane damage, and could damage the endoscope and/or instrument.

Olympus is pursuing the next generation of the Single Use Guide Sheath Kits, models K-401, K-402, K-403, and K-404, which has a different radiopaque tip design. Olympus will notify you when the K-401, K-402, K-403, and K-404 models are approved for sale in Malaysia.

### **Risk to Health:**

Sudden disassociation of the radiopaque marker from the main body of the guide sheath device while inside the patient during peripheral bronchoscopy can lead to potential patient harm. Consequences of a detached radiopaque marker include the risk of retained radiopaque marker in the tracheobronchial tree that may require urgent or non-urgent medical intervention for removal and the risk of bleeding, (either immediate or delayed). A prolonged procedure is expected to occur due to the need to either replace the device or proceed with medical intervention. If there is no alternative device replacement available, it could potentially result in the cancellation of the procedure. In any of the above-mentioned events, appropriate medical intervention/management should be based on the clinical circumstance.

**Actions Required:**

Our records indicate that your facility has received one or more affected units. Olympus requests you to take the following actions:

1. Carefully read the content of this FSN.
2. Ensure all personnel are completely knowledgeable and thoroughly trained on the content of this FSN and the Single Use Guide Sheath Kit Instructions for Use.
3. If you have further distributed this product, identify your customers, and forward them this notification.
4. Olympus requests that you acknowledge receipt of this FSN, by demonstrating that you have received and understood this notification by completing all available fields in the Reply Form and returning it back to your local Olympus representative latest by 30 May 2025.

Olympus requests that you report any complaints and adverse events experienced with the use of this product to Olympus.

Olympus fully appreciates your prompt cooperation in addressing this situation. If you require additional information, please do not hesitate to contact us.

**Contact for enquiries.**

Regulatory Affairs and Quality Assurance Department

Email : [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)

Tel : (603) 7650 8990

Fax : (603) 7650 8999

The **Medical Device Authority** has been informed of this notice.

Yours sincerely,

*Hideki Nagai*

.....  
Hideki Nagai  
Managing Director  
Olympus (Malaysia) Sdn. Bhd.

## Response Form

Please send the complete and signed Response Form to Regulatory Affairs and Quality Assurance Department at:

To : Olympus (Malaysia) Sdn. Bhd, Regulatory Affairs & Quality Assurance  
Fax/Email : (603) 7650 8999 / [mes-ra.oml@olympus.com](mailto:mes-ra.oml@olympus.com)  
From : \_\_\_\_\_ [Facility Name] Contact no.: \_\_\_\_\_  
Date : \_\_\_\_\_  
Ref : 2024-010M

### **URGENT - FIELD SAFETY NOTICE**

**Re: Olympus reminds users to closely follow the Instructions for Use (IFU) for the Single Use Guide Sheath Kits.**

I acknowledge receipt of the Field Safety Notice (“FSN”) referenced above. I confirm that I have further communicated to any affected departments.

Check the applicable boxes below:

- I DO NOT have affected product remaining. Product has been condemned or discarded.
- I DO have the affected product, which I will adhere to the Existing Instructions and Warnings from IFU.

#### **Additional Customer Requests:**

*(Indicate if you have any additional requests to support this action)*

Name: \_\_\_\_\_

Designation: \_\_\_\_\_

.....  
Signature & Company Stamp

.....  
Date






# 2024-010M FSN

Final Audit Report

2025-01-16

Created:	2025-01-16 (Australian Western Standard Time)
By:	Seo Ching Yeoh (seoching.yeoh@olympus.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAAuVtYI5jI9Gkz_8UWmHFpsSPiwwHOC5xz

## "2024-010M FSN" History

-  Document created by Seo Ching Yeoh (seoching.yeoh@olympus.com)  
2025-01-16 - 2:38:45 PM GMT+8- IP address: 165.225.230.97
-  Document emailed to Hideki Nagai (hideki.nagai@olympus.com) for signature  
2025-01-16 - 2:39:26 PM GMT+8
-  Email viewed by Hideki Nagai (hideki.nagai@olympus.com)  
2025-01-16 - 2:39:59 PM GMT+8- IP address: 210.19.151.50
-  Document e-signed by Hideki Nagai (hideki.nagai@olympus.com)  
Signature Date: 2025-01-16 - 2:44:19 PM GMT+8 - Time Source: server- IP address: 165.225.230.80
-  Agreement completed.  
2025-01-16 - 2:44:19 PM GMT+8